



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,059	05/22/2000	William J. Curatolo	PC8626BJTJ	2926

7590 03/26/2003
Gregg C Benson
PFIZER Inc
Eastern Point Road
Groton, CT 06340

EXAMINER

DEES, JOSE G

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 03/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,059

Applicant(s)

CURATOLO ET AL.

Examiner

Robert M DeWitty

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/25/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 77-148 is/are pending in the application.
- 4a) Of the above claim(s) 77-79, 87-92, 130-132 and 140-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-76, 80-86, 93-129, 133-139, and 146-148 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 77-148 are pending in the instant application. Claims 77-79, 87-92, 130-132, and 140-145 are withdrawn as being drawn to nonelected species.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 72-76, 80-86, 93-130, 133-139, and 146-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (U.S. Pat. No. 5,605,889), further in view of Handsfield et al., Urquhart (U.S. Pat. No. 4,851,231), and Edgren (U.S. Pat. No. 4,522,625).

Curatolo teaches a dosage form that can comprise from 25 mg to 3 grams of azithromycin (col. 4, lines 51-54). During in-vitro analysis utilizing USP-2 dissolution apparatus under the conditions of 900ml approx. 0.1M dibasic sodium phosphate buffer, pH 6.0, 37°C, with paddles turning at 100 rpm, the azithromycin dosage form of Curatolo et al. exhibits 90% dissolution within 15 minutes when an amount of the dosage form is equivalent to 200mg (col. 5, lines 27-35). The tablets can be film-coated with hydroxypropylmethylcellulose (col. 7, line 65-col. 8, line 2).

Handsfield teaches that 2.0 grams of azithromycin treat uncomplicated gonorrhea.

Urquhart teaches that certain drugs such as erythromycin should not be administered to the stomach but to the intestine over time.

Edgren teaches a dispenser for releasing drug formulations, such as in the gastrointestinal tract over a prolonged period of time. The dispenser is comprised of a body having a wall that surrounds an internal compartment, and can be shaped round or as a capsule. Passageways are included in the dispenser such as aperatures, orifices, bores, holes, and the like (col. 5, lines 32-34).

One with ordinary skill in the art would have been motivated to use 2 grams of azithromycin in a single dose in order to obtain the beneficial effects of using such a dosage amount (see Handsfield). Whereas Curtolo does not disclose the dissolution rate of the drug at 1 hour, 2 hour, 4 hour, etc. and that the dosage form is controlled release, Curatolo does disclose the dissolution time of a 200 mg dosage form, which corresponds to that of the instant invention. Thus, one with ordinary skill in the art would know a suitable dissolution rate for delivery azithromycin (which corresponds to the instant invention). One with ordinary skill in the art would have been motivated to administer a form at a dissolution rate taught by Curatolo to administer the dosage form to the gastrointestinal as opposed to the stomach.

Further to the above, the instant invention fails to claim the amount of azithromycin contained within the dosage form.

Response to Arguments

2. Applicant's arguments made in the Response have been considered but are nor persuasive.

Regarding the rejection under 35 U.S.C. 103(a), Applicant asserts that Curatolo 5,605,889 contrasts with the instant invention because Curatolo is related to immediate release dosage forms whereas Applicant's invention is directed to controlled release. The examiner would like to point out that Curatolo teaches release of 200 mg of the active ingredient in 15 minutes. The instant invention at claim 72 teaches the release of 200 mg of azithromycin in 15 minutes ($Q_{0.25}$). Whereas **889 may discuss immediate release and the instant invention may discuss controlled release, because they disclose the release of the same amount of active ingredient, it is the examiner's position that the two inventions are disclosing the same teachings. Thus, the rejection is maintained.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

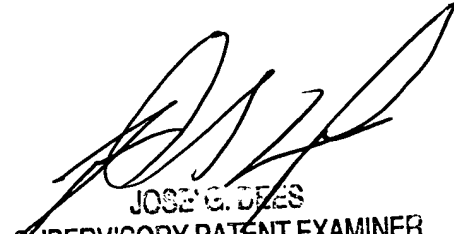
Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
March 12, 2003


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616